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October 25, 2005

Mr. Donald W. Jehn
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

RE: Blood Products Advisory Committee meeting Nov. 3-4, 2005 –
Approaches to OTC home-use HIV test kits

Dear Mr. Jehn:

American Medical Technologists (AMT) appreciates this opportunity to submit comments in connection with the Blood Products Advisory Committee's consideration of "approaches to over-the-counter (OTC) home-use HIV test kits" at BPAC's November 3 meeting.

AMT is a national, non-profit certification organization and membership society for clinical laboratory professionals and other allied health personnel. AMT currently has approximately 35,000 active members, who include medical technologists, medical laboratory technicians, medical assistants, phlebotomy technicians, and office laboratory technicians.

AMT is keenly aware of the importance of proper training and quality control for the performance of tests on human specimens. When testing for HIV, not only is the need for training and QC of heightened importance, but so is the need to have readily available counseling for individuals whose test results are positive. As the Committee is well aware, a positive result on an HIV test can be a life-changing event, and without the immediate availability of proper counseling, serious adverse consequences can ensue.

AMT is generally opposed to making HIV test kits available OTC for home use. Among the issues and concerns that would need to be thoroughly addressed before FDA approves such a product are the following:

- (1) An untrained person should not be performing such an important test. AMT believes that measures must be taken to insure that individuals who perform an OTC HIV test kit receive the requisite training, including training on follow-up procedures in the event of a positive preliminary result. In addition, there should

be negative and positive controls built into the system, so the person self-administering the test has some point of reference as to what a positive or negative result looks like.

(2) The ramifications of an erroneous result – whether a false positive or a false negative – can be potentially devastating. If, for example, the individual gets a false negative result, he may expose many other individuals in reliance on that result. What, if any, measures can be taken to eliminate the possibility that the test may be performed improperly?

(3) With OTC home-use testing, there is no assurance that a person who gets a positive result will take appropriate follow-up actions. The committee should thoroughly explore whether it is possible to provide necessary and appropriate counseling services in connection with OTC home-use HIV testing to insure that an individual testing positive does not commit suicide or avoid proper treatment and counseling for fear of disclosing his or her condition.

4) An OTC HIV test kit could be used for inappropriate purposes – *e.g.*, one person could purchase the kit and administer it to another individual without any legal limitation on the use of the results. A private individual who is not a healthcare provider is not subject to HIPAA privacy standards, and depending on individual State laws there may or may not be limits on the dissemination of a freely available OTC test result. Among other misuses of such information, a positive test result could be used to blackmail or defame someone on whom the test is administered.

AMT urges BPAC to give full consideration to these and other issues surrounding the concept of OTC home-use HIV test kits before making any recommendations on the potential approval of such products for home use. We thank the committee for the opportunity to submit comments.

Sincerely,

Michael N. McCarty
Michael N. McCarty
Legal Counsel

cc: John W. Sherer, MT, Chair,
Federal-Government Affairs Committee
Christopher A. Damon, JD, Executive Director